K053412



# 510(k) Summary

## General Company Information

**Schoelly Imaging, Inc.**
173 Grove Street
Worcester, MA 01605
James Bonneville, Operations Manager
508-425-6989

## General Device Information

**Product Name:** FlexiScope 50MH / 50MHC

**Common Name:** Light source for endoscope
Video camera and light source for endoscopic use (510(k)-exempt)

**Classification:** Light Source, Endoscope, Xenon Arc / GCT
Camera, Television, Endoscopic, without Audio / FWF (510(k)-exempt)

**Predicate Devices** AngioLaz Video Endoscopic System (K933868)
AMD Telemedicine AMD-300s Illumination & Imaging System (K940270)

**Indications for Use:**
The FlexiScope 50MH / 50MHC is indicated for use in conjunction with endoscopic devices to provide illumination and video visualization of optical images.

**Product Description:**
The Schoelly FlexiScope 50MH / 50MHC system is comprised of a camera handpiece and a combination light source / video processor; the system is intended for use with currently marketed endoscopes. The light source utilizes visible light to provide illumination of the area under endoscopic examination. The compact camera system component attaches to the proximal eyepiece of the user-supplied flexible or rigid endoscope. Images are optically captured via the endoscope. The image is transferred to the camera's CCD (charge coupled device) sensor through the scope objective lens, where it is converted to an electrical signal and amplified for output to accessories such as a monitor, printer, etc.

**Safety and Performance:**
Substantial equivalence for this device was based on a comparison of labeling, physical and performance design characteristics as compared to the predicate devices, as well as on the results of testing to establish compliance with international standards for electrical safety and electromagnetic compatibility (IEC 60601-1; IEC 60601-1-1; IEC 60601-1-2 & IEC 60601-2-18).

**Conclusion:**
Based on the indications for use, technological characteristics, and comparison to predicate devices, the Schoelly FlexiScope 50MH / 50MHC has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2006

Mr. David A. McNally
President
Schoelly Imaging, Inc.
173 Grove Street
WORCESTER MA 01605

Re: K053412
Trade/Device Name: FlexiScope 50MH / 50MHC
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCT and FCW
Regulation Number: 21 CFR §878.4160
Regulation Name: Surgical camera and accessories
Regulatory Class: Exempt
Product Code: FWF
Dated: January 30, 2006
Received: January 31, 2006

Dear Mr. McNally:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K053412

Device Name: FlexiScope 50MH / 50 MHC

Indications for Use:

The FlexiScope 50MH / 50MHC is indicated for use in conjunction with endoscopic devices to provide illumination and video visualization of optical images.

Prescription Use X AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053412